IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXACT SCIENCES CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 23-1319 (MN)
	)	
GENEOSCOPY, INC.,	)	
	)	
Defendant.	)	

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT GENEOSCOPY, INC.'S MOTION TO DISMISS

Of Counsel:

Kevin P.B. Johnson
Andrew J. Bramhall
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, CA 94065
(650) 801-5000

Sandra Haberny, Ph.D.
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
865 S. Figueroa Street, 10th Floor
Los Angeles, CA 90017
(213) 443-3000

Brian P. Biddinger
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Derek J. Fahnestock (#4705)
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
dfahnestock@morrisnichols.com

Attorneys for Plaintiff Exact Sciences Corporation

Dated: March 7, 2024

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Geneoscopy's motion to dismiss asks the Court to: (a) ignore the extensive, plausible allegations in Exact Sciences' First Amended Complaint ("FAC"); (b) disregard the Rule 12 standards and controlling law by resolving factual disputes in its favor; (c) abstain from exercising jurisdiction that the Court possesses; and (d) find that Exact Sciences has not raised more than the sheer possibility that Geneoscopy has acted unlawfully in its patent infringement, Lanham Act, and state law claims. None of Geneoscopy's arguments has merit. Exact Sciences has sufficiently pled each of its claims and the Court has jurisdiction to resolve them.

I. NATURE AND STAGE OF THE PROCEEDINGS

On November 17, 2023, Exact Sciences Corporation ("Exact Sciences") filed this action against Geneoscopy, Inc. ("Geneoscopy"), alleging infringement of U.S. Patent No. 11,634,781 (the "'781 Patent"). On January 12, 2024, Exact Sciences filed the FAC, adding claims under the Lanham Act, 15 U.S.C. § 1125(a), and Delaware state law. On February 8, 2024, Geneoscopy moved to dismiss the FAC under Rules 12(b)(1) and 12(b)(6). Exact Sciences opposes the motion.

II. SUMMARY OF THE ARGUMENT

Exact Sciences' FAC sufficiently pleads that: (a) Geneoscopy's at-home colorectal cancer ("CRC") screening test, ColoSense™, has infringed and will, upon FDA approval, infringe the '781 Patent; and (b) in marketing its infringing product, Geneoscopy has engaged in false advertising and unfair business practices through an extensive advertising campaign aimed to deceive doctors, patients, and others with misinformation about ColoSense's clinical performance. Geneoscopy's arguments that the Court should dismiss these claims fail uniformly.

First, Geneoscopy's reliance on the 35 U.S.C. § 271(e)(1) safe harbor is misplaced. In fact, Geneoscopy does not deny that it is prepared to launch ColoSense immediately upon FDA approval, which the complaint alleges Geneoscopy has repeatedly told the public will be imminent.

Geneoscopy ignores authority permitting a patentee to seek a declaration of future infringement, particularly where, as here, facts regarding the future infringement and its immediacy are pled with particularity. Geneoscopy's other attack on declaratory judgment jurisdiction is an irrelevant challenge to the merits of the substantive claims. Geneoscopy's extrinsic evidence does not dispute the imminency of the FDA approval and product launch of its ColoSense, which are the factual allegations the Court must assess to determine jurisdiction.

Second, Geneoscopy misapplies the law in arguing that an offer to sell the claimed methods cannot infringe, and ignores Exact Sciences' as-pled allegations, including a claim chart, showing that Geneoscopy has also infringed by ***using*** the claimed methods. Exact Sciences is only required to put Geneoscopy on notice as to how it is alleged to infringe, and does exactly that in the FAC.

Finally, Geneoscopy misses the point when it posits that the FDA and not the Court should evaluate the clinical data on ColoSense. The question is not whether Geneoscopy's clinical data on ColoSense supports FDA approval; it is whether Geneoscopy's ***advertising***—including advertising about what a scientific publication establishes and how it relates to ***Exact Sciences'*** product—is not only false and misleading, but has harmed, and will harm, Exact Sciences as a competitor. The Court is fully competent to decide that issue, which is not particularly within the discretion of the FDA. Exact Sciences' allegations in the FAC about Geneoscopy's ***advertising*** are more than sufficient to plead a false advertising claim and related state law claims.

III. STATEMENT OF FACTS

A. Exact Sciences, Cologuard, and the '781 Patent

Exact Sciences is a leader in the field of cancer screening and diagnostic tests. FAC ¶33. In 2014, Exact Sciences launched its flagship Cologuard® product, which was the first noninvasive stool-based (or fecal) nucleic acid CRC screening test approved by FDA. *Id.* ¶¶42, 44, 49. Cologuard, having been used by patients over 14 million times since 2014, has revolutionized CRC

early screening by providing average-risk patients with a convenient, accurate, and non-invasive at-home testing option. *Id.* ¶¶45-48.

Cologuard practices the claimed methods of Exact Sciences' '781 Patent. *Id.* ¶¶43, 63. The '781 Patent is directed to clinically important methods of processing fecal samples that enable, among other things, "mass screening of asymptomatic patients" for CRC and allow patient-friendly collection of fecal samples at home while preserving the integrity of biomarkers contained in the fecal samples for subsequent analysis in a laboratory. *Id.* ¶60.

B. Geneoscopy, ColoSense, and Geneoscopy's Infringing Acts

Geneoscopy has developed a competing at-home stool-based nucleic acid CRC screening test called ColoSense. *Id.* ¶¶65-68. Geneoscopy completed clinical trials for ColoSense, filed for FDA approval, and stated it expects FDA will approve its application imminently. *Id.* ¶¶73-77, 79, 81. Geneoscopy has also commenced meaningful preparations to commercially launch ColoSense immediately upon FDA approval, including signing a multi-year distribution agreement with LabCorp, building a scalable order management system for ColoSense, and posting job offers related to marketing and sale of ColoSense. *Id.* ¶¶72, 78-85.

Geneoscopy has already infringed the '781 Patent by commercially marketing, using, offering for sale, or selling ColoSense as a commercial laboratory developed test ("LDT") in or around July 2023 through an online website and order form. *Id.* ¶¶69-71, 99-125. In addition, Geneoscopy will infringe the '781 Patent by commercially marketing, making, using, offering for sale, and selling ColoSense upon the imminent FDA approval. *Id.* ¶¶72-86, 99-125.

C. Geneoscopy's False Advertising

Geneoscopy has advertised and promoted ColoSense with false claims that knowingly and materially misrepresent its clinical performance. *Id.* ¶126. Geneoscopy's advertising purports to rely on an unreliable and limited study—the Barnell Study, but it is not established by that study.

Id. ¶¶134-197. In particular, the FAC alleges Geneoscopy has made false and misleading statements about: (1) ColoSense's clinical sensitivity, *id.* ¶¶160-172; (2) its performance in the 45-49 age group, *id.* ¶¶173-179; (3) its purported superiority to other tests, including Cologuard, *id.* ¶¶180-188; (4) the purported superiority of RNA to DNA for detecting CRC, *id.* ¶¶189-192; and (5) ColoSense's clinical specificity, *id.* ¶¶193-197. Geneoscopy's false and misleading statements are material, *id.* ¶¶202-204, and have harmed, and will harm, Exact Sciences through, *e.g.*, loss of business relationships, customers, future revenues, and goodwill, *id.* ¶¶205-215.

IV. ARGUMENT

A. The Court Has Jurisdiction over Exact Sciences' Claim for Declaratory Judgment of Infringement (FAC Count II)

Geneoscopy moves under Rule 12(b)(1) to dismiss Exact Sciences' declaratory judgment claim for lack of subject matter jurisdiction. Mot. at 6-9. By arguing against the facts in the FAC and relying on extrinsic evidence (*see, e.g.*, Mot. at 8-9), Geneoscopy raises a factual attack on the Court's jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). But Geneoscopy fails to come forward with any facts that support a finding of lack of jurisdiction. Moreover, while "the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case," the Third Circuit has "repeatedly cautioned against allowing a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction to be turned into an attack on the merits." *Davis*, 824 F.3d at 346, 348 (quotations omitted).

1. The Safe Harbor Does Not Preclude Exact Sciences' Claim for Declaratory Judgment of Infringement

Geneoscopy argues there is no declaratory judgment jurisdiction because its activities are protected by the safe harbor of 35 U.S.C. § 271(e)(1). But the FAC is clear that Exact Sciences is not seeking to impose liability "based on any FDA approval activities falling within the safe harbor of 35 U.S.C. § 271(e)(1)." FAC ¶¶18, 88. Rather, the FAC's declaratory judgment claim alleges

that "Geneoscopy's ***imminent*** offer for sale, sale, distribution, manufacture, use and/or importation in the United States of the Accused Products . . . ***will infringe*** the '781 Patent." *Id.* ¶227. The declaratory judgment claim is based on Geneoscopy's imminent commercial activities following FDA approval, not activities related to obtaining FDA approval. Tus, the safe harbor is irrelevant.

"'A patentee may seek a declaration that a person will infringe a patent in the future.'" *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997)). "[D]eclaratory relief is available to the patentee," if "sufficient facts are alleged to create an actual case or controversy." *Glaxo*, 110 F.3d at 1571. Exact Sciences has pled sufficient facts showing a dispute concerning Geneoscopy's infringement that is "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Allergan, Inc. v. Revance Therapeutics, Inc.*, 2022 WL 2866723, at *4 (D. Del. July 21, 2022). In particular, the FAC alleges Geneoscopy has repeatedly stated that it is prepared to immediately launch ColoSense upon FDA approval, that it expects FDA approval within "the first half of 2024," and that it has "signed a multi-year agreement with LabCorp to distribute its ColoSense test upon FDA approval." FAC ¶¶15, 72-84. The FAC also alleges that the parties have communicated about Geneoscopy's infringement since May 2023, and that after being informed of its infringement Geneoscopy unsuccessfully sought to invalidate the '781 Patent through *ex parte* reexamination. *Id.* ¶¶16-17, 89-97. The totality of these allegations demonstrates the existence of a controversy of sufficient immediacy and reality to support a declaratory judgment. *Celphlon*, 2012 WL 682045, at *5 (declaratory judgment based on a defendant's activity directed toward infringement or meaningful preparation for such activity and a refusal to change course).

Geneoscopy relies on *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 2017 WL 2559735, at *2-3 (D. Del. June 13, 2017), to argue that the safe harbor precludes declaratory judgment claims

of infringement prior to FDA approval. Mot. at 6-7. That is not the law. The Court's decision in *Allergan* found that declaratory judgment jurisdiction existed ***before*** FDA approval and notwithstanding the safe harbor. *Allergan*, 2022 WL 2866723, at *4-5; *see also LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 2012 WL 2979028, at *6 (N.D. Cal. July 19, 2012) (holding court had declaratory judgment jurisdiction despite "uncertain" date of FDA approval because defendant's public statements "indicate[d] that that date will be imminent"). The Court in *Allergan* distinguished *Juno* and *Clarus Therapeutics, Inc. v. Lipocine, Inc.*, 2016 WL 5868065 (D. Del. Oct. 6, 2016), also cited by Geneoscopy, Mot. at 7, on the basis that those cases did not "involve an allegation of past infringement." 2022 WL 2866723, at *5. Moreover, in *Juno* and *Clarus*, the plaintiffs did not dispute that ***all*** of the defendant's activities were related to seeking FDA approval and did not "allege[] sufficient facts from which [the Court] could conclude that FDA approval of Defendant's [drug] is imminent or even certain." *Juno*, 2017 WL 2559735, at *2-3; *accord Clarus*, 2016 WL 5868065, at *2. In contrast, the FAC alleges past infringement by Geneoscopy, *infra* § IV.B, and sufficient facts demonstrating that FDA approval of ColoSense is imminent and Geneoscopy has made substantial preparations to infringe immediately upon FDA approval.[1]

As pled in the FAC, Geneoscopy's future infringement upon the imminent FDA approval do not fall within the safe harbor, and the totality of the allegations in the FAC demonstrates a sufficiently immediate and real controversy to warrant the issuance of a declaratory judgment.

2. Geneoscopy Fails to Overcome the Facts Alleged in the FAC Supporting Declaratory Judgment Jurisdiction

[1] Geneoscopy's other cases (Mot. at 7-8) are even less apposite, as the defendants were not even close to FDA approval. In *Intermedics, Inc. v. Ventritex Co.*, the district court granted ***summary judgment*** on a safe harbor defense based on activities while the defendants were engaged in clinical trials. 775 F. Supp. 1269, 1280 (N.D. Cal. 1991). In *Shaunnessey v. Monteris Med., Inc.*, the alleged infringer was ***several years away*** from submitting an ***application*** for FDA approval, so imminency for jurisdiction was lacking. 554 F. Supp. 2d 1321, 1323-24 (M.D. Fla. 2008).

Geneoscopy's factual attack on the Court's declaratory judgment jurisdiction consists mainly of arguments questioning the imminency of FDA approval and suggesting the approval process could "lead to changes in the proposed kit labelling or in its instructions for use." Mot. at 8. This is insufficient to overcome the facts alleged in the FAC, including Geneoscopy's own public statements about the timing of approval (FAC ¶¶76-81; Exs. L, M, N), and explanation why "Geneoscopy will provide the same or substantially the same instructions . . . to users or prospective users of its ColoSense upon FDA approval of the test." FAC ¶108. Indeed, although Geneoscopy submitted a declaration with its motion, D.I. 20, that declaration does not dispute that FDA approval is imminent or assert that there is any reason to believe the approval process may lead to changes in the accused sample collection process, the kit labelling, or instructions for use. As the court recognized in *Allergan*, if the factual allegations in the FAC were genuinely in dispute, "one might have expected [Geneoscopy] to mount a true factual challenge and submit evidence regarding its interactions with the FDA," but "it did not." *Allergan*, 2022 WL 2866723, at *5.[2]

Geneoscopy also cites a statement by Exact Sciences' CEO that "there's a lot of work to be done for these folks before they will earn the ability to serve patients and physicians." D.I. 21-2. That statement—which comes from Exact Sciences, not Geneoscopy—does not "cast doubt on how soon the FDA might approve ColoSense" (Mot. at 8), or undermine the immediacy of the parties' dispute. Simply put, this single statement cannot defeat the totality of the FAC's credible allegations, supported by evidence (including from Geneoscopy's principals, who are involved in the back and forth with the FDA), which demonstrate the existence of an immediate and real

[2] Geneoscopy cites *Amarin Pharms. Ireland Ltd. v. Omthera Pharms., Inc.*, to argue that declaratory judgment is "especially conjectural" because the '781 Patent only involves method claims. Mot. at 9. But *Amarin* found a lack of immediacy because the infringing product's launch date was "uncertain." 2014 U.S. Dist. LEXIS 205700, at *4 (D. Del. Nov. 14, 2014). Here, the FAC plausibly alleges that a commercial launch of ColoSense will occur imminently. FAC ¶15.

controversy. FAC ¶¶1, 15, 72-86, 103-125, 227; Exs. L, M, N, Q.

B. Exact Sciences Plausibly Alleges a Claim of Patent Infringement Based on Geneoscopy's Past Acts of Infringement (FAC Count I)[3]

Geneoscopy moves under Rule 12(b)(6) to dismiss Exact Sciences' claim for past infringement solely because the FAC purportedly does not allege sufficient facts showing Geneoscopy has ***sold or offered to sell*** ColoSense. Mot. at 9-11. In a ruling under Rule 12(b)(6), a district court is not permitted to go beyond the facts alleged in the Complaint and supporting documents.[4] *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1424-25 (3d Cir. 1997).

Geneoscopy's motion ignores the FAC's allegations that Geneoscopy has infringed by commercially ***using*** the claimed methods. For example, the FAC alleges Geneoscopy "commercially marketed, ***used***, offered for sale, and/or sold the ColoSense product, including related kits, devices, and services, as a commercial laboratory developed test, or LDT, in or around July 2023," it "developed the accused ColoSense for at-home CRC screening . . . ***using the fecal sample processing methods claimed in the '781 Patent***," and it "has infringed . . . by commercially manufacturing, ***using***, marketing, offering for sale, selling, and/or importing Geneoscopy's CRC screening products."[5] FAC ¶¶67-69; *see also id.* ¶¶85, 103, 107, 218-19. The FAC also includes claim charts showing, on an element-by-element basis, how use of ColoSense

---

[3] Exact Sciences did not "jettison[] its allegation of present infringement." Mot. at 5. Rather, Geneoscopy took down its website and associated order form. FAC ¶¶69-71.

[4] Exact Sciences' complaint must plead "enough factual matter" that, when taken as true, "state[s] a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 670 (2007). This plausibility standard is met when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[5] LDTs are *in vitro* diagnostic products intended for clinical use in the testing of specimens taken from the human body, and are used within a single clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests. LDTs are exempt from FDA oversight. *See Illumina, Inc. v. Fed. Trade Comm'n*, 88 F.4th 1036, 1045 n.1 (5th Cir. 2023).

results in performance of all of the steps of at least claims 1 and 3. D.I. 15, Ex. F. These allegations, which Geneoscopy's motion fails to address, are "sufficient to put [Geneoscopy] on notice as to how their use of [ColoSense] constitutes direct infringement," which is all that is required. *Dodots Licensing Sols. LLC v. Lenovo Holding Co., Inc.*, 2018 WL 6629709, *3 (D. Del. Dec. 19, 2018).

Moreover, Geneoscopy is incorrect that a sale or offer for sale cannot infringe a method claim as a matter of law. Exact Sciences acknowledges that there are district court decisions, including from this Court, holding that a party cannot infringe under section 271(a) by offering to sell or selling a method. Respectfully, however, the Federal Circuit has explicitly left open the question whether one can infringe a method claim through a sale or offer for sale. *NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d 1282, 1320-21 (Fed. Cir. 2005) ("We need not and do not hold that method claims may not be infringed under the 'sells' and 'offers to sell' prongs of section 271(a)."). There are also multiple district court decisions holding that a method claim can be infringed through an offer for sale. *See CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 667 F. Supp. 2d 29, 37-38 (D.D.C. 2009) (denying motion for summary judgment that accused infringer could not have infringed method claims by making an offer for sale); *Optigen, LLC v. Int'l Genetics, Inc.*, 777 F. Supp. 2d 390, 402-03 (N.D.N.Y. 2011) (similar); *WesternGeco L.L.C. v. ION Geophysical Corp.*, 869 F. Supp. 2d 793, 798-99 (S.D. Tex. 2012) (similar). Indeed, there is nothing in the statutory language of 35 U.S.C. § 271(a) indicating that "any patented invention" was intended to apply only to apparatus inventions with respect to an offer to sell or sale. And, as other courts have noted, given that the Supreme Court held in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), that a method can be sold for purposes of "patent exhaustion," there is no persuasive reason why a method cannot also be sold for infringement purposes.

C. Exact Sciences Plausibly Alleges False Advertising Under the Lanham Act

Geneoscopy's motion mischaracterizes Exact Sciences' false advertising claim in an

attempt to evade it. ***First***, Geneoscopy's primary-jurisdiction arguments fail because Exact Sciences' Lanham Act claim is not a back-door attack on the FDA's authority to evaluate the clinical efficacy of, or to approve, ColoSense (Mot. at 12). Rather, Exact Sciences contends that Geneoscopy's ***commercial marketing and promotion*** of ColoSense include false and misleading statements about its clinical performance that have harmed, or are likely to harm, Exact Sciences.

Second, Geneoscopy's other attacks on the Lanham Act claim similarly fail. The FAC contends that Geneoscopy's commercial advertising claims regarding ColoSense are literally false or at a minimum misleading, and that those advertising claims are not supported nor established by the Barnell Study. *See, e.g.*, *Eastman Chem. Co. v. Plastipure, Inc*., 775 F.3d 230, 236 (5th Cir. 2014); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *CareDx, Inc. v. Natera, Inc.*, 2019 WL 7037799, at *8 (D. Del. Dec. 20, 2019). Moreover, the FAC plausibly alleges the remaining elements for the false advertising claim: Geneoscopy's false statements are material insofar as they are likely to impact customer purchasing decisions, have affected interstate commerce, and have caused, and are likely to cause, injury to Exact Sciences. FAC ¶¶198-215.

1. <u>The Court Should Not Abstain From Exercising Jurisdiction</u>

The Court should not abstain from exercising jurisdiction over Exact Sciences' Lanham Act claim on primary jurisdiction grounds. Federal courts "have a 'virtually unflagging obligation . . . to exercise the jurisdiction given them'" and, therefore, a decision to abstain "is the exception rather than the rule." *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011). Because Exact Sciences' Lanham Act claim does not require "the resolution of issues which . . . have been placed within the special competence of" the FDA, abstention would be improper. *Id.*

Geneoscopy argues that Exact Sciences' false advertising claims are an "attack on Geneoscopy's clinical data" that "fall within the special expertise of the FDA." Mot at 11. Geneoscopy ignores the "distinction between respecting the FDA's primary jurisdiction to

determine in the first instance whether a drug is lawfully marketed and, on the other hand, a Lanham Act claim that a false statement has been made about a product." *G&W Lab'ys, Inc. v. Laser Pharms., LLC*, 2018 WL 3031943, at *9 (D.N.J. June 19, 2018) (citation omitted). Exact Sciences is not attempting to usurp the FDA's authority. The claims aim to hold a competitor liable for false and misleading commercial statements that have caused, and will continue to cause, harm to Exact Sciences' business and reputation. As the Supreme Court found, "[w]hen two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statue to preclude the operation of the other . . . The Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102, 115 (2014).

Here, the FAC plausibly alleges Geneoscopy has violated the Lanham Act by making false and misleading claims ***about ColoSense in its commercial marketing and promotion*** that "are not established by the Barnell Study," FAC ¶157, and that Exact Sciences ***has been harmed*** and is ***entitled to remedies*** as a result of those false and misleading claims. *Id.* ¶¶19-20, 205-215, 246-247, 261.[6] For example, Geneoscopy has made false and misleading claims about the purported sensitivity and specificity of ColoSense that are not established by the Barnell study (*id.* ¶¶128-129, 134-153, 160-172), as well as claims of superiority of ColoSense over Cologuard despite lacking any basis in ***any study*** (including the Barnell Study) to make such comparisons (*id.* ¶¶180-188). The FDA will not evaluate whether Geneoscopy's false and misleading statements have resulted in harm to Exact Sciences.[7]

---

[6] "In determining whether to invoke primary jurisdiction . . . [a]t the motion to dismiss stage," the question is "whether the complaint plausibly asserts a claim that would not implicate the doctrine." *Cnty. of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1237, 1252 (9th Cir. 2009), *rev'd on other grounds*, 563 U.S. 110 (2011).

[7] The circumstances here are distinguishable from *Endo Pharms., Inc. v. Actavis, Inc.* (cited in

Geneoscopy argues that the *Baykeeper* factors weigh in favor of dismissal because "[t]he FDA will independently evaluate ColoSense's efficacy and the validity of its underlying clinical data." Mot. at 12. Not so. "The first [*Baykeeper*] factor focuses on the competence of the court and the agency to address the matter." 660 F.3d at 691. "While [the FDA] has expertise in [drug and medical device safety] matters" a claim for false advertising under the Lanham Act "is not peculiarly within the agency's area of expertise, but is one which the courts or jury are equally well-suited to determine." *Id.* Indeed, there is an entire body of caselaw pertaining to establishment claims under the Lanham Act, which is within the competence of the courts. *See, e.g.*, *CareDx*, 2019 WL 7037799 (denying motion to dismiss Lanham Act establishment claim relating to diagnostic tests subject to FDA approval).

Similarly, the second *Baykeeper* factor, "whether the matter is particularly within the discretion" of the FDA, weighs against abstention because false advertising is not "particularly within" the FDA's discretion. 660 F.3d at 691-92. Indeed, the FAC does not allege that any claim by Geneoscopy violates any element of the Federal Food, Drug, and Cosmetic Act (FDCA), and the FDA ***will not*** address the harm to Exact Sciences caused by Geneoscopy's advertising or the appropriate remedy associated with that harm. *See, e.g.*, *Cipla USA, Inc. v. Ipsen Biopharm., Inc.*, 2023 WL 4013542, at *5 (D. Del. June 15, 2023) (finding first two *Baykeeper* factors weigh against abstention where Lanham Act claim did not ask the Court to determine medical coding); *Caldon, Inc. v. Adv. Measurement & Analysis Grp., Inc.*, 515 F. Supp. 2d 565, 574 (W.D. Pa. 2007) (denying motion to dismiss Lanham Act claim based on the primary jurisdiction doctrine because the issue of whether defendants "ha[d] misrepresented the accuracy of their [device] and

Mot. at 12-13), which involved a manufacturer filing an FDA application raising the issue of drug equivalency and the related claims. 2013 WL 4774494, at *3 (D.N.J. Sept. 3, 2013).

disparaged Plaintiff's device" was "within the competence of th[e] Court").

The third *Baykeeper* factor also weighs in Exact Sciences' favor because there is no danger of inconsistent rulings. In deciding whether to approve ColoSense the FDA will determine whether the clinical data shows that ColoSense is safe and effective for the consuming public. It will not determine whether, *e.g.*, Geneoscopy's advertising has caused, and will continue to cause, harm to Exact Sciences or the appropriate remedy associated with that harm. Indeed, the FDA's approval of ColoSense will have no impact at all on Exact Sciences' Lanham Act claim.

As to the fourth *Baykeeper* factor, there is no basis to conclude from the FAC that any "prior application to the agency has been made." *Baykeeper*, 660 F.3d at 691. Geneoscopy refers to an erroneous footnote in a since corrected version of the FAC (D.I. 21-3) to speculate about an FDA trade complaint "that presumably raises the same issues." Mot. at 12. Neither the footnote nor any trade complaint are part of the pleadings and, as such, cannot provide a basis for the Court to abstain from exercising jurisdiction. In any event, "this single factor cannot outweigh the others that disfavor abstention on primary jurisdiction grounds." *Baykeeper*, 660 F.3d at 692.

Ultimately, the question of whether Geneoscopy "has violated the Lanham Act by making false statements about [ColoSense] is within this Court's purview, regardless of whether [ColoSense] has been approved or unapproved by the FDA." *G&W Lab'ys*, 2018 WL 3031943, at *8. As such, abstention based on the doctrine of primary jurisdiction is not warranted.

2. Exact Sciences Has Standing For Its Lanham Act Claim

Whether Exact Sciences has established Geneoscopy's statements as the proximate cause of its harm under the Lanham Act is a question of statutory standing, assessed under Rule 12(b)(6), rather than a question of subjection matter jurisdiction under Rule 12(b)(1). *CareDx*, 2019 WL 7037799, at *3. The Lanham Act explicitly authorizes suit by any plaintiff that believes that he or she is ***likely*** to be damaged by a defendant's false advertising. *See Lexmark*, 572 U.S. at 129. The

Lanham Act protects against both *past and future harm*. *Id.* at 131. The Third Circuit has held that a Lanham Act plaintiff need not prove actual loss, but only a reasonable basis to believe it is likely to suffer injury. *Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 95-97 (3d Cir. 2000).

Even before Geneoscopy launches ColoSense, Geneoscopy's statements about its competing product, and comparisons to Exact Sciences' product, can proximately cause injury to Exact Sciences. In *CareDx*, the plaintiff alleged the defendant, who was "in the midst of launching" its competing medical test,[8] violated the Lanham Act by making statements comparing its clinical study with the results of the plaintiff's clinical study despite the absence of a head-to-head study. 2019 WL 7037799. The defendant moved to dismiss, arguing that because the defendant "*never sold* any product that compete[d] with" plaintiff's product it was impossible for consumers to be deceived and, therefore, there was no actual harm. *Id.* at *5 (emphasis in original). The Court disagreed, holding the Lanham Act plaintiff plausibly alleged proximate cause despite "not point[ing] to a specific, already-lost sale" because it alleged the defendant's statements "have harmed and will continue to harm [the plaintiff] through loss of goodwill, reputation, profits, and prospective business contracts." *Id.* at *6-7.

Here, the FAC pled facts "plausibly indicating that [Geneoscopy's] statements about [Exact Sciences'] product will likely cause the plaintiff economic harm in the future." *Id.* at *5. For example, Geneoscopy's press releases, promotional presentations, and other statements tout ColoSense's purported superiority as compared to Cologuard, actively soliciting sales from current

[8] Geneoscopy attempts to distinguish *CareDx* on the basis that "the plaintiff was not awaiting FDA approval and there was no dispute that commercial launch was imminent." Mot. at 14 n.5. Presumably Geneoscopy means the *defendant* was not awaiting FDA approval, as Exact Sciences, like the *CareDx* plaintiff, have FDA-approved tests. FAC ¶¶44, 49, 183; *CareDx*, 2019 WL 7037799, at *1. In any event, the FAC's allegations, accepted as true, allow the reasonable inference Geneoscopy's commercial launch of ColoSense is imminent. FAC ¶¶15, 76-77, 84, 126.

Cologuard customers in anticipation of ColoSense's imminent launch. FAC ¶¶180-188. Such statements threaten Exact Sciences' sales and are damaging to its reputation, *id.* ¶¶206-209, 211-212, regardless of whether ColoSense is currently sold.[9] *See, e.g.*, *CareDx*, 2019 WL 7037799, at *6-7 ("That this 'competition' is of a type where the parties' products are not *both* being sold (but likely will be soon) is not a barrier to setting out proximate cause.") (emphasis in original).

In light of the above, it is no surprise that Geneoscopy's cited cases (Mot. at 13-14) is factually inapposite. In each of *PDK Labs*, *Alphamed Pharms.*, and *Martin*, the Lanham Act claimants did not have competing products on the market so they were unable to make claims based on injury to commercial interest in that product, and in some cases the defendants also did not have competing products.[10] In contrast, Exact Sciences' product has been on the market for almost a decade, and approval of Geneoscopy's product is imminent. FAC ¶¶7, 15, 44, 76-77. And unlike *Nespresso USA, Inc. v. Ethical Coffee Co. SA*, where the Court denied a motion to amend to add a Lanham Act claim because of a failure to plead a connection between generalized statements about environmental impact and the alleged injury, in this case, Exact Sciences has pled that Geneoscopy's false and misleading claims necessarily implicate Cologuard and have already impacted Exact Sciences' reputation and goodwill. 2017 WL 3021066, at *4 (D. Del. July 14,

[9] Geneoscopy's citation to a declaration outside the pleadings (Mot. at 4-5, 14 (citing D.I. 20)) is improper and should be disregarded. *See, e.g.*, *CareDx*, 2019 WL 7037799, at *4 n.4 (in adjudicating a motion to dismiss, refusing to consider declaration from Lanham Act defendant that referenced statements made by plaintiff's CEO that were not alleged in the complaint).

[10] *See PDK Labs.*, 103 F.3d 1105, 1112 n.7 (2d Cir. 1997) (Lanham Act claimant lacked standing because it was "unclear when (if ever) [it] w[ould] have an FDA-approved, marketable [competing] consumer product" to establish a causal nexus for any injury); *Alphamed Pharms. Corp. v. Arriva Pharms., Inc.*, 391 F. Supp. 2d 1148, 1161-65 (S.D. Fla. 2005) (finding no competitive injury where *neither* party had a product on the market); *Martin v. Wendy's Int'l, Inc.*, 183 F. Supp. 3d 925, 933 (N.D. Ill. 2016)((holding Lanham Act claimant lacked standing because he "ha[d] not settled on a merchantable model of which to launch production, and he ha[d] no more than a 'verbal agreement' to participate in bringing any product to market at all.").

2017) (finding "no facts pled that plausibly allege a link between ECC's lost sales or goodwill and Nespresso's statements about the environmental impact of its capsules."); FAC ¶¶180-188.

3. Exact Sciences Has Pled Facts Sufficient To Show That Geneoscopy's False and Deceptive Advertising Violates the Lanham Act

False advertising under the Lanham Act requires: (1) the defendant made false or misleading statements as to its own product or another's; (2) actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the advertised goods traveled in interstate commerce; and (5) a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *CareDx*, 2019 WL 7037799, at *7. The FAC plausibly alleges facts to support each element.

False and Deceptive Advertising. Geneoscopy argues that "courts do not recognize a private right of action for advertising that allegedly lacks substantiation." Mot. at 15. The cases Geneoscopy cites, however, are inapposite because they involve state law consumer fraud, not Lanham Act, claims. "A plaintiff may satisfy its burden of showing that an establishment claim is false or misleading under the Lanham Act by proving that the tests referred to in the advertisement were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." *CareDx*, 2019 WL 7037799, at *8. The FAC details multiple false and misleading statements about ColoSense's clinical performance and unsupported comparisons with Cologuard, and explains in detail why these statements are not supported by the Barnell Study. FAC ¶¶126-197. This is more than sufficient to plead the first element of a Lanham Act claim. *See, e.g.*, *CareDx*, 2019 WL 7037799, at *8-9.

Geneoscopy attempts to excuse its deceptive claims as a "scientific disagreement." Mot. at 15-16. Advertisements, however, "do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate." *Eastman Chem.*, 775 F.3d at 236. And

Exact Sciences does not merely disagree with Geneoscopy's claims—it alleges they are knowingly false and misleading. FAC ¶¶126-197. For example, Geneoscopy's superiority claims comparing ColoSense and Cologuard are not a scientific debate; they falsely reflect an implied head-to-head comparison without the support of a head-to-head study or comparable data. FAC ¶¶127, 183-184, & n.97, Exs. H, I. Where, like here, no study establishes "the proposition asserted by the defendant, the plaintiff has obviously met its burden of demonstrating literal falsity." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997) (internal quotation marks omitted).

Geneoscopy's argument that its false advertising falls within a purported "safe harbor" established by the Second Circuit in *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, is without merit. Mot. at 15 (citing 720 F.3d 490, 496 (2d Cir. 2013)). Unlike *ONY*, Exact Sciences' claim is not premised only on false or misleading statements in the Barnell Study, but rather on Geneoscopy's statements in advertising that misrepresent and are not established by the Barnell Study. FAC ¶¶157-197. Although the FAC contains a detailed discussion of the failings of the Barnell Study (*see* FAC ¶¶134-156), it does so to support the allegations that Geneoscopy's advertising claims "are not established by the Barnell Study or any other published study on ColoSense." FAC ¶157. For example, the FAC alleges Geneoscopy made false and misleading claims of "100% CRC sensitivity" without disclosing that the study only analyzed five cancers in the 45-49 age group. *Id.* ¶¶173-179. This District, and others, have found that *ONY* does not preclude claims against false or misleading promotional statements referencing a study. *CareDx*, 2019 WL 7037799, at *9;[11] *Eastman*, 775 F.3d at 236 ("This lawsuit is not about Dr. Bittner's scientific paper. It is about

[11] *See also Guardant Health, Inc. v. Natera, Inc.*, 580 F. Supp. 3d 691, 708 (N.D. Cal. 2022) ("Where false advertising claims allege that the [defendant's] study's conclusions are based on inaccurate descriptions of the data and methodology, the claims can be grounds for a claim under the Lanham Act.").

statements made in commercial advertisements or promotions, not statements made in a peer-reviewed journal.").

Deception. Exact Sciences has alleged Geneoscopy has made literally false statements by, *inter alia*, comparing ColoSense with "available" competitors (i.e., Cologuard). FAC ¶181. Courts "have repeatedly determined that when a defendant makes comparative statements based on testing that is flawed and unreliable, those statements . . . are appropriately viewed as literally false statements." *CareDx*, 2019 WL 7037799, at *10 (collecting cases). Having alleged literal falsity, Exact Sciences is entitled to a presumption of deception. *See, e.g.*, *id.*; *N. Atl. Imports, LLC v. Loco-Crazy Good Cookers, Inc.*, 2024 WL 245955, at *2 (D. Del. Jan. 23, 2024).

Geneoscopy argues it "does not refer to Cologuard by name in its comparative claims." Mot. at 19. But "there need not be a direct comparison to a competitor for a statement to be actionable under the Lanham Act." *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993). False statements comparing products to those of competitors by implication are actionable. *Id.*. That applies to Geneoscopy's false statements referring to "other 'available' noninvasive screening tests," of which Cologuard undisputedly is the leading alternative. FAC ¶181.

Even absent the presumption of deception, Exact Sciences' allegations are sufficient. As Geneoscopy recognizes, Exact Sciences has alleged intended end-users of at-home CRC screening tests, doctors, and other stakeholders are likely to be deceived by Geneoscopy's statements. FAC ¶¶206-209. Geneoscopy disputes these allegations, arguing physicians are unlikely to be deceived, Mot. at 17, but a motion to dismiss is not the place to resolve factual disputes. *See Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022). Similarly, Geneoscopy's argument (Mot. at 17) that Exact Sciences' reference to an article from GenomeWeb is "irrelevant" to any consumer deception misses the mark as the article, which describes the advertising by Geneoscopy, demonstrates others

have been misled by Geneoscopy's advertising in precisely the way that Exact Sciences alleges.[12]

Materiality. Geneoscopy is wrong in asserting that Exact Sciences cannot allege materiality as a matter of law because ColoSense is not on the market. Mot. at 18. As explained above, Exact Sciences need not wait until it is actually harmed as the Lanham Act expressly permits a party "who believes that he or she is or is *likely* to be damaged" to bring an action. 15 U.S.C. § 1125(a)(1) (emphasis added). Nor must Exact Sciences "plead customer reliance at the time of the purchasing decision" to allege materiality of Geneoscopy's false and misleading statements. *N. Atl. Imports*, 2024 WL 245955, at *3. Rather, Exact Sciences need only allege facts which, "in the light most favorable to [it]," allow the Court "to [reasonably] infer that customers would consider [Geneoscopy's] false advertisements material to their purchasing decisions." *Id.*; *see also Enzo Life Scis., Inc. v. Digene Corp.*, 295 F. Supp. 2d 424, 428 (D. Del. 2003).

Geneoscopy's false statements are material. For example, by suggesting ColoSense is superior to its direct competitor Cologuard, Geneoscopy's false statements are likely to affect purchasing decisions. FAC ¶¶204, 210-215, 239. Furthermore, Geneoscopy's false and misleading statements regarding the sensitivity of ColoSense relate to a key characteristic of CRC screening tests. *Id.* ¶¶126-172, 193-197. These allegations regarding materiality are sufficient to withstand a motion to dismiss. *See, e.g.*, *N. Atl. Imports*, 2024 WL 245955, at *3 (holding plaintiff plausibly alleged false advertisements of competing product were likely to influence customer decisions).

Injury. Geneoscopy incorporates the same arguments regarding Exact Sciences' standing under the Lanham Act to contend Exact Sciences has not shown injury. Mot. at 18. Geneoscopy's

[12] *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, which involved an appeal of a denial of a motion for a preliminary injunction, has no bearing on whether Exact Sciences has plausibly alleged a Lanham Act claim, including the element of deception. *Compare* 902 F.2d 222, 229-30 (3d Cir. 1990) (addressing the "sufficiency of evidence" for a Lanham Act claim), *with CareDx*, 2019 WL 7037799, at *7, *10 (pleading Lanham Act claim).

position is meritless for the reasons set forth above. *Supra*, § IV.C.1; *see also, e.g.*, *Breathasure*, 204 F.3d at 95-96 (noting that a reasonable basis for a believing false advertising will cause injury generally equates with a reasonable showing of a likelihood of future harm under the Lanham Act).

D. Exact Sciences Plausibly Alleges Violations of the Delaware Unfair or Deceptive Trade Practices Act ("DTPA")

Geneoscopy seeks dismissal of the DTPA count for the same reasons as the Lanham Act count. Mot. at 19. Because the FAC adequately pleads a Lanham Act claim, *supra*, § IV.C, Exact Sciences also sufficiently states a DTPA claim. *E.g.*, *N. Atl. Imports*, 2024 WL 245955, at *4 (holding plaintiff sufficiently alleged DTPA false advertising claim because it adequately stated a Lanham Act claim); *Treasury Mgmt. Servs., Inc. v. Wall Street Sys. Del., Inc.*, 2017 WL 1821114, at *5 (D. Del. May 5, 2017) (declining to dismiss a DTPA claim based on the conclusion that the Lanham Act claim was sufficiently pleaded).

E. Exact Sciences Plausibly Alleges Unfair Competition

Geneoscopy argues Exact Sciences' unfair competition claim does not identify a specific party prepared to enter into a business relationship nor plead facts showing Geneoscopy interfered with such a relationship. Mot. at 20. This distorts applicable law. Exact Sciences has plausibly alleged "(1) it had a reasonable expectancy of entering into business relationships with patients and healthcare providers; (2) [Geneoscopy's] allegedly false and misleading statements likely have and will continue to deceive patients and healthcare providers (as well as insurance companies and the general public); and (3) harm has and will result by preventing [Exact Sciences] from earning revenue and building goodwill." *See CareDx*, 2019 WL 7037799, at *13; FAC ¶¶205-215.

V. CONCLUSION

For the foregoing reasons, Geneoscopy's motion to dismiss should be denied.

Dated: March 7, 2024

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
dfahnestock@morrisnichols.com

Attorneys for Plaintiff Exact Sciences Corporation

OF COUNSEL:

Kevin P.B. Johnson
Andrew J. Bramhall
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, CA 94065
(650) 801-5000

Sandra Haberny, Ph.D.
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
865 S. Figueroa Street, 10th Floor
Los Angeles, CA 90017
(213) 443-3000

Brian P. Biddinger
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 7, 2024, upon the following in the manner indicated:

Steven J. Balick, Esquire — *VIA ELECTRONIC MAIL*
Andrew C. Mayo, Esquire
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
Attorneys for Defendant

Donald R. Ware, Esquire — *VIA ELECTRONIC MAIL*
Sarah S. Burg, Esquire
FOLEY HOAG LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210-2600
Attorneys for Defendant

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)